IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9098

Bartle, J. June 26, 2013

Janice M. Chaffins ("Ms. Chaffins" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

---

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In December, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, David Bayne, M.D. Based on an echocardiogram dated March 11, 2002, Dr. Bayne attested in Part II of claimant's Green Form that Ms. Chaffins suffered from moderate mitral regurgitation and a reduced ejection fraction in the range of 50% to 60%. Based on

---

2. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

such findings claimant would be entitled to Matrix A-1, Level II benefits in the amount of $500,195.[3]

In the report of claimant's echocardiogram, the reviewing cardiologist, Karl C. Stajduhar, M.D., stated that Ms. Chaffins had "[m]oderate mitral regurgitation." Dr. Stajduhar, however, did not specify a percentage as to claimant's level of mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In September, 2005, the Trust forwarded the claim for review by Irmina Gradus-Pizlo, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Gradus-Pizlo concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Gradus-Pizlo explained, "No color scale on the digital images[.] One view in the long axis view is suggestive of

---

3. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). Although the Trust disputes that claimant had a reduced ejection fraction, which is one of the complicating factors needed for a Level II claim, we need not resolve this issue given our determination with respect to claimant's level of mitral regurgitation.

moderate [mitral regurgitation] but the jet lasts only for two frames and clearly is not persistent through systole."

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination denying the claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[4] In contest, claimant submitted a letter from Stuart W. Zarich, M.D., F.A.C.C., F.A.S.E., F.A.H.A., wherein he agreed with the attesting physician that Ms. Chaffins had moderate mitral regurgitation. In his letter, Dr. Zarich stated:

> ... [T]here is moderate mitral regurgitation in the apical views, although the degree of mitral regurgitation is difficult to access in other views. However, there are several indirect echocardiographic signs that support the diagnosis of moderate mitral regurgitation. First of all, as agreed on by the auditing cardiologist[,] left ventricular function is hyperdynamic which is one of the hallmarks of mitral regurgitation. Second, the left atrial size is well out of portion for any abnormalities in left ventricular diastolic function, which is typically seen in patients with mitral regurgitation. As there is no left ventricular hypertrophy one would not expect such an enlarged left atrium without regurgitation. Finally, there is mild to moderate pulmonary hypertension which is also quite consistent with moderate mitral insufficiency. I disagree wholeheartedly with ... the criticism of the reviewer that

---

4. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to this claim.

> the mitral regurgitation lasts for only two frames and is not persistent through out systole. There are clearly technical difficulties so the mitral regurgitation is not seen on all frames, however, it does persist through systole (as would be expected for all degrees of mitral insufficiency[])].

The Trust then issued a final post-audit determination, again denying the claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the claim should be paid. On March 3, 2010, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8408 (Mar. 3, 2010).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on November 17, 2010. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[5] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause

---

5. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Chaffins repeats the arguments she made in contest; namely, that the opinions of Dr. Bayne and Dr. Zarich, as well as the finding of the reviewing cardiologist, Dr. Stajduhar, provide a reasonable medical basis for the finding of moderate mitral regurgitation.[6]

---

6. Claimant also argued that the report of a July 6, 2001 echocardiogram supports her claim. As the July 6, 2001 echocardiogram does not establish a reasonable medical basis for (continued...)

In response, the Trust argues that the opinions of claimant's physicians do not establish a reasonable medical basis for her claim simply because she "collect[ed] more opinions." The Trust also notes that claimant did not identify any specific errors in the conclusion of the auditing cardiologist. In addition, the Trust argues that neither claimant nor her experts identified a "holosytolic jet of mitral regurgitation that appears in consecutive frames and meets the 20% ratio required by the Settlement Agreement." Finally, the Trust contends that Dr. Gradus-Pizlo performed her review of claimant's March 11, 2002 echocardiogram in accordance with the Audit Rules.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Specifically, Dr. Vigilante explained:

> I reviewed the CD of the Claimant's echocardiogram of attestation. This CD demonstrated 26 digital loops/images.... This study was not performed in accordance with the usual medical standards. There is markedly increased color gain with color artifact noted within the myocardial tissues and even outside of the heart. In addition, this was an incomplete study presentation. There was no documentation of the apical two chamber view and no documentation of the continuous wave Doppler of the tricuspid regurgitant jet. The Nyquist limit was not

---

6. (...continued)
the attesting physician's Green Form representation of moderate mitral regurgitation based on the March 11, 2002 echocardiogram, it is irrelevant to our disposition.

> documented on these color Doppler loops. In addition, there was only one loop that demonstrated the mitral regurgitatant jet in the apical four chamber view. As there was no apical two chamber view, mitral regurgitation was not documented in this view. In addition, the left atrium was measured in a non-qualifying parasternal short-axis view rather than the parasternal long-axis view on this study.
>
> .... Visually, there was some degree of mitral regurgitation noted in the parasternal long-axis view and in the apical four chamber view. I was unable to accurately determine the RJA in the one apical four chamber loop in which the mitral regurgitant jet was noted. The jet appeared to be somewhat smaller after the first two frames of systole. However, due to excessive color gain and the absence of the Nyquist limit settings, it was not possible to determine the RJA. I was able to planimeter the LAA in the apical four chamber view. I determined that the LAA in the apical four chamber view was 18.0 cm2. There are no images of the apical two chamber view on the study. There are no sonographer-determined RJAs or LAAs on this study.[7]

After reviewing the entire Show Cause record, we find claimant's arguments are without merit. Contrary to claimant's assertion, the opinions of her cardiologists do not provide a reasonable medical basis for her claim. We are required to apply the standards delineated in the Settlement Agreement and Audit Rules. The context of these two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends and one that must be applied on a case-by-case

---

7. Dr. Vigilante also observed that there was no reasonable medical basis for the attesting physician's representation that Ms. Chaffins had a reduced ejection fraction because her echocardiogram demonstrated an ejection fraction of 67%.

basis. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating the echocardiogram setting; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002).

Here, Dr. Gradus-Pizlo reviewed claimant's echocardiogram and determined that it demonstrated only mild mitral regurgitation. She noted that there was "[n]o color scale on the digital images" and that the only jet that appeared "suggestive of moderate [mitral regurgitation] ... lasts only for two frames and clearly is not persistent through systole." Although claimant's expert, Dr. Zarich, disputed the auditing cardiologist's conclusion that the mitral regurgitation did not persist throughout systole, he did not address Dr. Gradus-Pizlo's determinations regarding the absence of color scale on the digital images. Dr. Vigilante also reviewed claimant's echocardiogram and determined that it did not demonstrate moderate mitral regurgitation. He explained that he was unable to determine the RJA "due to excessive color gain and the absence

of the Nyquist limit settings." Dr. Vigilante also noted that "[t]he jet appeared to be somewhat smaller after the first two frames of systole." Finally, Dr. Vigilante observed that "the left atrium was measured in a non-qualifying parasternal short-axis view rather than the parasternal long-axis view."[8] Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation that claimant suffered from moderate mitral regurgitation.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of the claim of Ms. Chaffins for Matrix Benefits.

---

8. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.